

## REMARKS

### Amendments to the Claims

Claims 1-17, 31-43, 48-61, 63, 67-73 93, 94, 99-101, 114-121 and 123-135 are pending. The Applicant thanks the Examiner for withdrawing the restriction requirement against Claims 48-53. The Applicant respectfully asks the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 1-12, 14-16, 31-35, 48, 51, 52, 54, 55, 58-61, 114, 115, 118-121, 123, 124, 127-131, and 136 were amended. Claims 137-139 are new. The Applicant states that all amended claims do not add new subject matter to the present specification.

Amendment support for Claims 1 and 12 can be found at, *e.g.*, ¶ 83, ¶ 84, ¶ 87, and Example IX.

Amendment support for Claims 137-139 can be found at, *e.g.*, original Claims 14-16.

### Summary of Interview Pursuant to 37 C.F.R. § 1.133(b)

The Applicant wishes to thank the Examiner for the telephone interview on August 7, 2007. Pending Claims 1-17, 31-43, 48-61, 63, 67-73 93, 94, 99-101, 114-121 and 123-135 were discussed in view of the outstanding rejection alleging a lack enablement pursuant 35 U.S.C. § 112, ¶ 1 and anticipation pursuant 35 U.S.C. § 102(b).

The Examiner and the Applicants agreed that, amending the claims as indicated below should be sufficient to overcome the pending rejections.

### Claim Objection

The Examiner has objected to Claims 2-11 as being of improper dependent form for failing to further limit the subject matter of Claim 1 because each dependant claim recites the phrase "an amino acid sequence selected from the group consisting of."

As per the telephone interview, present Claims 2-10 were amended to recite "said amino acid sequence selected from the group consisting of," whereas Claim 11 was amended to recite "said first BoNT/A peptide consists essentially of amino acids 785-803 of SEQ ID NO: 1." Thus, the Applicant respectfully submits that amended Claims 2-11 are in proper dependent form and requests withdrawal of the objection against Claims 2-11.

## **Rejection Pursuant to 35 U.S.C. 112, ¶ 1 Enablement Rejection**

### ***I. Immunogens capable of stimulating an immune response***

The Examiner has rejected Claims 31-43, 84-92 and 114-122 as allegedly lacking enablement under 35 U.S.C. §112, ¶1. The Examiner contends that the previous amended peptide compositions comprising 6 amino acids in size is not enabling for stimulating an immune response because a peptide of 6 amino acids is considered a hapten since it would have a molecular weight of less than 1000 daltons and haptens are not recognized as immunogens capable of stimulating an immune response. The Applicants respectfully ask for reconsideration under 37 C.F.R. §1.111.

Currently amended Claims 31-43, 84-92 and 114-122 are directed, in part, to peptide comprising at least eight amino acids. A peptide of eight amino acids has an average molecular weight over 1000 daltons (average amino acid weight being 135 daltons) and thus would be considered immunogens capable of stimulating an immune response. Thus the Applicant submits that presently amended claims are enabled and respectfully request withdrawal of the 35 U.S.C. §112, ¶1 enablement rejection against Claims 31-43, 84-92 and 114-122.

### ***II. Peptides capable of detecting or stimulating an immune response***

The Examiner has rejected Claims 1-11, 12-13, 14-17, 31-43, 54-61, 63, 67-73, 114-121, 123-133 and 136 as allegedly lacking enablement under 35 U.S.C. §112, ¶ 1. The Examiner contends that while being enabling for methods and compositions for the induction of an immune response and detection of antibodies to BoNT/A peptides, the specification "does not reasonably provide enablement for detection of or induction of an immune response through

using a peptide that is an immunoreactive fragment or conservative variant, or a peptide that is not large enough to stimulate an immune response thereto the recited peptides." See pg. 6, ¶ 2, lines 1-7, May 17, 2007 Office Action.

As per the telephone interview, present Claims 1-11, 12-13, 14-17, 31-43, 54-61, 63, 67-73, 114-121, 123-133 and 136 were amended to delete the phrase "an amino acid sequence selected from the group consisting of." Thus the Applicant submits that presently amended claims are enabled and respectfully request withdrawal of the 35 U.S.C. §112, ¶1 enablement rejection against Claims 1-11, 12-13, 14-17, 31-43, 54-61, 63, 67-73, 114-121, 123-133 and 136.

#### **Rejection Pursuant to 35 U.S.C. 112, ¶ 2 Indefiniteness**

##### ***I. "at least one said BoNT/A peptides"***

The Examiner has rejected Claims 1-11 and 14-17 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as his invention because the phrase "wherein the presence of antibodies immunoreactive with at least said first BoNT/A peptide or said second BoNT/A peptide indicates immuno-resistance to a botulinum toxin therapy" is internally inconsistent and unclear. The Applicant respectfully asks for reconsideration pursuant to 37 C.F.R. § 1.111.

Amended Claim 1 recites "wherein the presence of antibodies immunoreactive with said first BoNT/A peptide and said second BoNT/A peptide indicates immuno-resistance to a botulinum toxin therapy." Thus, the Applicant respectfully submits that amended Claim 1 is definite and requests withdrawal of the 35 U.S.C. § 112, ¶ 2 indefiniteness rejection against Claims 1-11 and 14-17.

##### ***II. "wherein two of said additional BoNT/A peptides"***

The Examiner has rejected Claims 10 and 11 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 because the limitation "wherein two of said additional BoNT/A peptides" lacks sufficient antecedent basis to Claim 1 and are unclear.

Amended Claims 10 and 11 recite "wherein said first BoNT/A peptide." Thus, the Applicant respectfully submits that the amended claims are definite and requests withdrawal of the 35 U.S.C. § 112, ¶ 2 indefiniteness rejection against Claims 10 and 11.

### ***III. "determining"***

The Examiner has rejected Claim 14 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 because the limitation "determining" lacks sufficient antecedent basis to Claim 1 and is unclear.

Amended Claim 14 recites "detecting." Thus, the Applicant respectfully submits that the amended claims are definite and requests withdrawal of the 35 U.S.C. § 112, ¶ 2 indefiniteness rejection against Claim 14.

## **Rejection Pursuant to 35 U.S.C. § 102(b)**

### ***I. Tugnoli Reference in light of Domlimbek Reference***

The Examiner has rejected Claims 1-14, 17 and 136 as allegedly anticipated under 35 U.S.C. §102(b) by Valeria Tugnoli et al., *The Therapeutic Use of Botulinum Toxin*, 6(10) Exp. Opin. Invest. Drugs 1383-1394 (1997), hereafter the "Tugnoli reference" in light of evidence provided by Behzod Z. Dolimbek et al., *Mapping of the Regions on the Heavy Chain of Botulinum Neurotoxin A (BoNT/A) Recognized by Antibodies of Cervical Dystonia Patients with Immuno-resistance to BoNT/A*, 44(5) Mol. Immunol. 1029-1041 (2007), hereafter the "Domlimbek reference." The Applicant respectfully asks for reconsideration pursuant to 37 C.F.R. § 1.111.

As per the telephone interview, present Claims 1-14, 17 and 136 were amended to recite, in part, the step of "contacting a first BoNT/A peptide and a second BoNT/A peptide with a test specimen from said individual." Thus the Applicant submits that the presently amended claims are not anticipated by the Tugnoli reference and respectfully request withdrawal of the 35 U.S.C. §112, ¶1 anticipation rejection against Claims 1-14, 17 and 136.

## CONCLUSION

For the above reasons the Applicant respectfully submits that the claims are in condition for allowance, and the Applicant respectfully urges the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent. Please use Deposit Account 01-0885 for the payment of any extension of time fees pursuant to 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

/Dean G. Stathakis/

Dean G. Stathakis, Ph.D.  
Registration No. 54,465  
Agent of Record



**ALLERGAN**

**LEGAL DEPARTMENT**

2525 Dupont Drive  
Irvine, California 92612-1599  
Tel: 714/246-6521  
Fax: 714/246-4249